



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: March 3, 2022

SUBJECT: Efficacy Review for Virex 24,
EPA Reg. No. 70627-IL
Submission: 1075276
E-submission No. 67684
Action Code Case: 00322100

FROM: Atinuke Onyonyor
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: December 27, 2021

THRU: Kristen Willis, Chief
Efficacy Branch
Antimicrobials Division (7510P)
Date Signed: March 3, 2022

TO: Eric Miederhoff, PM/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: Diversey Inc.
P.O. Box 19747
Charlotte, NC 28219-0747

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (50% C14, 40% C12, 10% C16%)	
dimethyl benzyl ammonium chloride	0.25%
Didecyl dimethyl ammonium chloride	0.25%
<u>Other Ingredients</u>	99.50%
<u>Total</u>	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: New Registration

Currently registered efficacy claim(s): N/A

Requested action(s): Registrant is requesting new product registration for Virex 24 (EPA File Symbol 70627-IL) as a ready-to-use (RTU) spray disinfectant (bactericide, virucide, mildewcide) for hard, non-porous surfaces, non-food contact surface sanitizer, and 24-hour residual surface sanitizer and is citing data from DV 5-26762 (*previously EPA File Symbol 4564-ET*).

Documents considered in this review:

- Cover letter from applicant to EPA dated 9/10/2021
- Terms of Registration letter dated 9/10/2021
- Proposed label dated 9/13/2021
- Data Matrix (EPA Form 8570-35) dated 9/8/2021
- Confidential Statement of Formula for (EPA Form 8670-4) for Virex 24, *EPA File Symbol 70627-IL* dated 9/6/2021
- Confidential Statement of Formula (Alternative Formulation #1) (EPA Form 8670-4) for DV 5-26762, *previously EPA File Symbol 4564-ET* dated 3/10/2021
- Amended AD Efficacy Review DV 5-26762 *previously EPA File Symbol 4564-ET* E-sub: 61498 Action Code Case: 00294299 dated 9/28/2021

Note: Per DV 5-26762 (*previously EPA File Symbol 4564-ET*) technical screen dated 5/25/2021, MRIDs 51481618 and -19 were not reviewed as these studies do not align with the agency's guidance for supporting a residual disinfection claim. Consistent with EPA Guideline 810.2200, *Staphylococcus aureus* (ATCC No. 6538) and *Pseudomonas aeruginosa* (ATCC No. 15442) should be used to support the case residual disinfectant claim. Data for *Pseudomonas aeruginosa* was not submitted to support the residual disinfectant claim.

MRIDs 51481618 and -19 were not reviewed for this submission consistent with the reason identified for DV 5-26762.

II AGENCY STANDARDS FOR PROPOSED CLAIMS

Agency Standards for Making Viral Emerging Pathogen Claims in accordance with the agency publication *Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens not on EPA-registered Disinfectant Labels*:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, non-porous surfaces.
2. The currently accepted product label should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:

<i>For an emerging viral pathogen that is a/an...</i>	<i>Qualifying criterion</i>
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Enveloped virus emerging viral pathogen	At least one large OR one small non-enveloped virus
Large, non-enveloped emerging viral pathogen	At least one small, non-enveloped virus
Small, non-enveloped emerging viral pathogen	At least two small, non-enveloped viruses with each from a different viral family

III PROPOSED DIRECTIONS FOR USE

For Use as a (One-Step) (Cleaner)/(Disinfectant)(Sanitizer)(Non-Food Contact Sanitizer):

1. Hold container 6"-8" from surface and spray until visibly wet
2. All surfaces must remain visibly wet for 5 minute.
3. Allow to air dry (or rinse (with potable water if necessary)).

Note: All food contact surfaces must be rinsed with potable water. Do not use on glassware, utensils, or dishes.

For use as a Sanitizer:

1. Pre-clean visibly soiled areas.
2. Apply Solution with spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain visibly wet for 1 minute.
4. Wipe surfaces dry (or rinse) (or allow to air dry).
5. Change solution after each use (application).

For use as a Sanitizer for 24 Hours:

1. Pre-clean visibly soiled areas.
2. Apply Solution with spray, cloth, disposable wipe or mop to hard, non-porous environmental surfaces.
3. Allow the surface to remain visibly wet for five minutes.
4. Allow to air dry.

Animal Housing Facilities (Including Veterinary Clinics, (Equine) Farms, Livestock, Swine and Poultry Houses): For cleaning and disinfecting the following hard, non-porous surfaces: feeding and watering equipment, utensils, instruments, cages, kennels, stables, catteries, etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities (including pens, chutes, and barns) occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding or watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with potable water. Apply product to hard, non-porous environmental surfaces.
5. All surfaces must remain visibly wet for 5 minutes.
6. Allow to air dry (or rinse (with potable water if necessary)).
7. Ventilate buildings and other closed spaces.
8. Do not house animals or employ equipment until treatment has been set or dried.

NOTE: Not for use on handling and restraining equipment such as leashes, muzzles, halters or ropes, as well as forks, shovels, and scrapers used for removing litter and manure.

IV STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51481610	Non-Food Contact Sanitizer	Hard, non-porous surfaces	RTU Liquid	60 seconds	5% FBS	N/A	<ul style="list-style-type: none"> Klebsiella aeruginosa ATCC 4352 Staphylococcus aureus ATCC 6538 	Yes
51481611	Disinfectant, virucidal	Hard, non-porous surfaces	RTU Liquid	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Human Rotavirus ATCC VR-2018 Strain WA 	Yes
51481612	Disinfectant, virucidal	Hard, non-porous surfaces	RTU Liquid	10 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Human Rotavirus ATCC VR-2018, Strain WA 	Yes
51481613	Residual Self-Sanitizing Activity of Dried Chemical Residues	Hard, non-porous surfaces	RTU Liquid	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Klebsiella aeruginosa ATCC 4352 Staphylococcus aureus ATCC 6538 	Yes
51481614	Disinfectant, bactericidal	Hard, non-porous surfaces	RTU Spray	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Pseudomonas aeruginosa ATCC 15442 	Yes
51481615	Disinfectant, bactericidal	Hard, non-porous surfaces	RTU Spray	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Staphylococcus aureus ATCC 6538 	Yes
51481616	Disinfectant, bactericidal	Hard, non-porous surfaces	RTU Spray	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Salmonella enterica ATCC 10708 	Yes
51481617	Disinfectant, virucidal	Hard, non-porous surfaces	RTU Liquid	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> Influenza A H1N1 Strain A/WS/33 ATCC VR-1520 Human Respiratory Syncytial Virus, Strain Long HRSV, ATCC VR-26 Coronavirus Strain 229E ATCC VR-740 	Yes

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51481620	Disinfectant, virucidal	Hard, non-porous surface	RTU Liquid	5 minutes	5% FBS	N/A	<ul style="list-style-type: none"> SARS-CoV-2, Strain USA-WA 1/2020 (BEI Resources NR-52281) 	Yes

*Cited from EPA Reg No. AD Efficacy Review DV 5-26762 *previously EPA File Symbol* 4564-ET dated 9/7/2021 (includes MRIDs 51481610-51481617 & 51481620)

EMERGING VIRAL PATHOGEN CONCLUSIONS

MRID (year)	Emerging virus claim	Organism(s)	Type of Virus (family)	Surface Type	Application Method(s), Dilution, and Diluent	Contact Time	Soil load	Data supports EVP claim(s)?
51481611	Enveloped Viruses	Human Rotavirus, ATCC VR-2018, Strain WA	Large, non-enveloped	Hard non-porous surface	Ready-to-Use liquid	5 minutes	5% FBS	Yes

VI LABEL COMMENTS

Label Date: 9/13/2021, EPA File Symbol 70627-IL

1. The proposed label claims that the product referenced above, when applied as a RTU liquid is an effective sanitizer against the following on visibly clean non-food contact, hard, non-porous surfaces for a 60-second contact time:

Klebsiella pneumoniae (ATCC 4352)
Staphylococcus aureus (ATCC 6538)

MRID 514816-10
MRID 514816-10

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

2. The proposed label claims that the product referenced above, when applied as a RTU liquid is an effective residual self-sanitizer for up to 24 hours against the following on visibly clean, non-food contact, hard, non-porous surfaces for a 5-minute contact time:

Klebsiella pneumoniae (ATCC 4352)
Staphylococcus aureus (ATCC 6538)

MRID 514816-13
MRID 514816-13

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

3. The proposed label claims that the product referenced above, when applied as a RTU liquid is an effective virucidal disinfectant against the following on hard, non-porous surfaces with a 5% soil load at a 5-minute contact time:

Human Rotavirus (ATCC VR-2018) Strain WA
Influenza A H1N1 Strain A/WS/33 (ATCC VR-1520)
Human Respiratory Syncytial Virus, strain Long
(HRSV; ATCC VR-26)
Coronavirus strain 229E (ATCC VR-740)
SARS-CoV-2, strain USA-WA1/2020 (BEI Resources NR-52281)

MRID 514816-11
MRID 514816-17
MRID 514816-17
MRID 514816-17
MRID 514816-17
MRID 514816-20

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

4. The proposed label claims that the product referenced above, when applied as a RTU spray, is an effective virucidal disinfectant against the following on visibly clean, hard, non-porous surfaces for a 10-minute contact time:

Human Rotavirus (ATCC VR-2018) Strain WA

MRID 514816-12

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

5. The proposed label claims that the product referenced above, when applied as a RTU spray, is an effective disinfectant against the following bacteria on visibly clean, hard, non-porous surfaces for a 5-minute contact time:

Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

MRID 514816-14
MRID 514816-15
MRID 514816-16

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

6. The proposed label claims that the product, Virex 24, (EPA File Symbol 70627-IL) qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to the EPA dated September 10, 2021:

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Human Rotavirus, ATCC-VR 2018, Strain WA

These claims are **acceptable** as they are supported by the cited data from DV 5-26762 (EPA File Symbol 4564-ET).

Virex 24, [Insert EPA Reg. No]
Date: [insert date]

As per Attachment I of the GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS, W.M. Barr & Company, Inc, agrees to the following terms of registration:

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories.

- Enveloped virus

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Human Rotavirus, ATCC-VR 2018, Strain WA

- followed by the 4 statements from Attachment I of the EVP guidance.

Please revise the emerging viral pathogens statement in the Terms of Registration letter dated 9/10/2021 as follows.

- Remove "large non-enveloped virus"

7. Make the following changes to the proposed label:

1. Throughout the proposed label,
 - a. mentions of COVID-19 virus should be qualified with the appropriate footnote to link COVID-19 to SARS-CoV-2.
 - b. each virucidal, virucide, or virus claim on the label should be linked to the specific virus tested. This may be indicated using an asterisk or footnote.

- c. each residual surface sanitizer claim on the label should be linked to the specific organisms tested. This may be indicated using an asterisk or footnote.
 - d. ensure one-step pesticidal claims are linked to the appropriate use directions (e.g. “when used according to disinfection directions”)
 - e. Remove references to USA-WA when referencing SARS-CoV-2 consistent with WHO recommendations that strains names should not include references to specific locations.
 - f. All references to “germ” or “germs” or “germicidal” should be appropriately qualified consistent with the following as this product was not tested against fungi:
 - i. <https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>
 - g. Remove all claims for “mildewcide”. No data was submitted to substantiate this claim. Claims for odors caused my mildew are acceptable.
2. On page 1 of the proposed label,
 - a. revise the word “disinectant” to disinfectant”.
 - b. Remove “shield” as this product is not a residual disinfectant.
 3. On page 2 of the proposed label,
 - a. remove “virtually all” or add a qualifier appropriately linking to referenced surfaces.
 - b. Qualify the following with “when used according to disinfection directions”
 - i. “One-step disinfectant (Cleaner) (& Deodorizer)”
 - ii. “multi-surface [one-step] disinfectant”
 - iii. “1 step cleaning and disinfection”
 - c. Remove “sanitizer” from the following claim:
 - i. “Broad-spectrum (Multi-purpose) (Multi-surface) (Bactericidal) (*Virucidal) (Sanitizer) (Disinfectant) (activity)”
 4. On page 3 of the proposed label,
 - a. appropriately link the statement “kills (99.9% of) germs in 5 minutes” to the referenced organisms.
 - b. appropriately link the statement “kills (99.9% of) the cold and flu viruses” to the referenced organisms.
 - c. remove “effective against SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in 1 minutes] on hard non-porous surfaces” or revise to include the appropriate contact time established in testing (5 mins).
 5. On page 4 of the proposed label,
 - a. Remove “powerful” from the claim “Powerful cleaning and disinfection in 5 minute” as it implies heightened efficacy.
 - b. Remove “fungicide” from the claim “Proven “one-step” disinfectant/cleaner/fungicide/mildewcide/virucide that is effective for hard, non-porous surfaces”. This product has not met the criteria in the 810.2200 guideline to make claims as a fungicide. In addition, qualify with “when used according to the directions for disinfection”
 6. On page 5 of the proposed label,
 - a. Revise the claim “24 hour protection even after [with] multiple touches” to “24 hour protection of surfaces....” And “24 hours of protection from bacteria

growth [even in high contact areas]* *Even after multiple touches” to “24 hours of protection for surfaces...”

- i. Claims that imply protection from disease are not permitted.
 - b. add a qualifier to appropriately link the following statements to their corresponding organisms
 - i. “kills 99.9% of bacteria for 24 hours on treated surfaces.”
 - ii. “kills 99.9% of bacteria in 5 minutes and keeps killing for 24 hours.”
 - c. Remove “pathogens” from the claim “Tough on germs (pathogens)”
 - d. Remove the claims “24 hour peace of mind” and “A product that gives you [24 hours peace of mind]” as these imply heightened efficacy
 - e. Remove “germ” from the following claims as only disinfectant claims can be linked to germ claims per the link to the germ policy provided above:
 - i. “24 hour (bacteria) (germ) (pathogen) sanitization”
 - ii. “All day (bacteria) (germ) (pathogen) protection”
7. On page 6 of the proposed label,
 - a. Revise the claim “Sanitize and protect for 24 hours” to specify that the product protects surfaces.
8. On page 7 of the proposed label,
 - a. Remove “mildew” from the following claim “[This product can be used against bacteria, *viruses, and mildew on hard non-porous surfaces found in: {insert use sites from list below}]]”
9. On page 12 of the proposed label
 - a. appliances that should be brought to room temperature before product application, such as stove[top]s, instant warmers, dryers and freezer exteriors, should indicate “allow surfaces to reach room temperature prior to treatment”.
10. On page 13 of the proposed label,
 - a. remove “[Faster Contact Times]” as this statement may imply heightened efficacy.
11. On page 15 of the proposed label
 - a. remove large, non-enveloped viruses.